

Remarks

I. Support for Amendment

The foregoing amendment to the specification embodies a revision of formal matters as requested by the Examiner, and places the application in better form for allowance. Accordingly, this amendment does not add new matter to the application, and its entry and consideration is respectfully requested.

II. Status of the Claims

Claims 100-127 are pending in the application, with claims 100-102, 118 and 119 being the independent claims.

III. Summary of the Office Action

In the Office Action dated October 3, 2002, the Examiner has objected to the specification for an allegedly improper claim to priority and has made one rejection of the claims. Applicants respectfully offer the following remarks to overcome or traverse each of these rejections.

IV. The Objection to the Statement of Priority is Accommodated

In the Office Action at page 2, the Examiner has objected to the specification, asserting that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120. The Examiner's objection is based on Applicants reference to "related" applications 08/663,002 and 08/486,139 in the first line of

the instant application without disclosing in what way these applications are related to the instant application. Additionally, the Examiner has pointed out that no claim to priority of these documents is noted in the declaration.

By the foregoing amendments, the references to the earlier stated "related applications" have been deleted. Hence, this objection has been fully accommodated. Reconsideration and withdrawal are respectfully requested.

V. *The Rejection under 35 U.S.C. § 103*

In the Office Action at pages 3-5, the Examiner has rejected claims 100-127 under 35 U.S.C. §103(a) as being unpatentable over Hartley *et al.* (WO 96/40724, of record as Doc. No. AO1; hereinafter "Hartley") in view of Shuman (U.S. Patent No. 5,766,891, of record as Doc. No. A; hereinafter "Shuman"). Applicants respectfully traverse this rejection.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time the invention was made. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1995). Instead, what is needed is a reason, suggestion, or motivation in the prior art that would motivate one of ordinary skill to combine the cited

references, and that would also suggest a reasonable likelihood of success in making or using the claimed invention as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case, the Examiner's burden has not been satisfied.

Hartley discloses a method for recombinational cloning using recombination sites. Shuman discloses a method of cloning PCR products using vaccinia topoisomerase by including a 10-nucleotide sequence at the 5' end of two primers used for amplification to generate duplex molecules which contain the specified sequence at both 3' ends (column 6, lines 44-54). The Examiner asserts that Shuman discloses the use of primers with specific sequences to amplify nucleic acid molecules comprising those specific sequences for use in cloning procedures (*see Office Action at page 5*). The Examiner goes on to conclude that the ordinary skilled artisan would have been motivated to combine the teachings of Hartley with Shuman to develop a cloning system that was free of the use of restriction endonucleases, theorizing that it would have been obvious to combine these teachings because the addition of recognition sequences to primers for the purpose of cloning is a convenient way of modifying the sequences to contain elements of interest, which is allegedly described in Shuman. Applicants respectfully disagree with these assertions.

The mere fact that Hartley discloses sequences for recombination, while Shuman describes the use of primers with specific unrelated sequences does not render the instant invention obvious. The fact that some of the sequences disclosed in Hartley are also recited in the present claims is irrelevant to the obviousness of the present claims, since these sequences are not themselves the point of novelty or nonobviousness of the claimed invention. As noted above, absent some suggestion and/or motivation, the cited references may not be properly combined to render the claimed invention obvious. *See In re Fine*, 5

USPQ2d 1596, 1598 (Fed. Cir. 1988). Here, the Examiner merely states that it would be "convenient" to combine the disclosures of the cited references, without pointing to any suggestion or motivation to do so in the references themselves. According to the Federal Circuit, there are three permissible sources for a motivation to combine references: "the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *See In re Rouffet*, 47 USPQ2d 1453, 1457-58(Fed. Cir. 1998). Applicants respectfully contend that the Examiner has not shown any of these sources to be present in the cited references, which therefore may not be properly combined under *Fine*. 5 USPQ2d 1596 (Fed. Cir. 1988).

In making this rejection, the Examiner appears to be relying on hindsight in combining these references in arriving at an obviousness determination. As the Federal Circuit has held numerous times, such a hindsight analysis is impermissible. Instead, the Examiner must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) ("When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself."); *Fine*, 5 USPQ2d at 1600 ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."); *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) (noting that use of an applicant's specification as though it were prior art to support an obviousness determination is legal error); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (holding that both the suggestion to combine references, and a reasonable expectation of

success in making the claimed invention, “must be found in the prior art, not in the Applicant’s disclosure.”). The Board has also provided the same mandate on this issue:

it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious a rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

Ex parte Haymond, 41 USPQ2d 1217, 1220 (Bd. Pat. App. Int. 1996). As discussed above, the Examiner has not pointed to anything in Hartley or Shuman which provides any motivation to combine their disclosures. The fact that Hartley and Shuman were in existence at the time the instant application was filed, without more, is not sufficient for a finding of obviousness. Thus, the hindsight analysis used in the present case is impermissible and cannot be used to attempt to establish a *prima facie* case of obviousness.

The Examiner also appears to contend that the use of the specific sequences which were recited in Hartley would have rendered the claimed invention inherently obvious:

Hartley, *et al.*, discloses sequences that are identical to each of those of the instant application, thereby anticipating the sequences (for example SEQ ID No. 5 of the instant application is 100% identical to SEQ ID No. 5 of WO 96/40724, and SEQ ID No. 39 is identical to SEQ ID No. 6 of WO 96/40724 because the variable nucleic acid residues of SEQ ID No. 39 read on those that are present in SEQ ID No. 6). Furthermore, these sequences are derived from *att* recombination sites and have the inherent property that they will not all recombine with each other (owing to differences in the individual sequences; see page 43, lines 24-25 of the instant application), therefore those limitations are also anticipated by the identity of these sequences. In addition, the *att* recombination sites contain multiple stop codons and have the ability to form hairpin structures (see

page 41-42 of the instant application) that are eliminated by the mutations defined in the sequences disclosed in the instant application. Therefore, the sequences disclosed in Hartley, *et al.*, inherently have these properties due to sequence identity with the sequences of the instant application.

Office Action at pages 4, line 16 to page 5, line 6 (emphasis in original). Applicants wish to remind the Examiner, however, that there is no such thing as "inherent obviousness," since inherency and obviousness are different legal concepts. *See In re Spormann*, 150 USPQ 449, 452 (C.C.P.A. 1966). That which is inherent cannot be obvious, since inherent information "is not necessarily known....[and] Obviousness cannot be predicated on what is unknown." *Id.* Since the present rejection is based on obviousness, any contention by the Examiner that is based on the possible presence of inherent knowledge in Hartley must necessarily fail.

Thus, the Examiner has not met the burden required to sustain a *prima facie* case of obviousness. Applicants respectfully submit that the rejection of claims 100-127 under §103(a) has been overcome; withdrawal and reconsideration are therefore respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply, and allowance of all pending claims, are respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

In the Specification:

The paragraph beginning on page 1, line 6 has been deleted and replaced with the following paragraph:

The present application claims the benefit of the filing date of U.S. Provisional Application No. 60/065,930, filed October 24, 1997, the disclosure of which is incorporated by reference herein in its entirety.